

Food and Drug Administration Rockville, MD 20857

December 21, 2004

FILE COPY

Vy Tran Varian Medical Systems, Inc. 3100 Hansen Way Palo Alto, CA 94304-1038

Dear Mr. Tran:

Your petition requesting the Food and Drug Administration to approve a variance for Acuity, K033339 and On Board Imaging, K042720 Optional Therapy Simulation Systems, was received by this office on 12/16/2004. It was assigned docket number 2004V-0553/VAR1 and it was filed on 12/21/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe

Division of Dockets Management Office of Management Programs

Office of Management

20041-0553

ACK 1